UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

BRIAN ROBINSON, Derivatively on Behalf of OCULAR THERAPEUTIX, INC.,	Case No.
Plaintiff, v. AMARPREET SAWHNEY, CHARLES WARDEN, RICHARD L. LINDSTROM, JASWINDER CHADHA, BRUCE A. PEACOCK, JEFFREY S. HEIER, W. JAMES O'SHEA, ERIC ANKERUD, JAMES GARVEY, GEORGE MIGAUSKY, and W. BRADFORD SMITH,	VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT FOR BREACH OF FIDUCIARY DUTY, WASTE OF CORPORATE ASSETS, AND UNJUST ENRICHMENT
Defendants,	
OCULAR THERAPEUTIX, INC., a Delaware corporation,	
Nominal Defendant.	DEMAND FOR JURY TRIAL

Plaintiff, by his attorneys, submits this Verified Stockholder Derivative Complaint for Breach of Fiduciary Duty, Waste of Corporate Assets, and Unjust Enrichment. Plaintiff alleges the following on information and belief, except as to the allegations specifically pertaining to plaintiff which are based on personal knowledge. This complaint is also based on the investigation of plaintiff's counsel, which included, among other things, a review of public filings with the U.S. Securities and Exchange Commission ("SEC") and a review of news reports, press releases, and other publicly available sources.

NATURE AND SUMMARY OF THE ACTION

1. This is a stockholder derivative action brought by plaintiff on behalf of nominal defendant Ocular Therapeutix, Inc. ("Ocular" or the "Company") against certain of its officers and directors for breaches of fiduciary duties, waste of corporate assets, unjust enrichment, and

violations of law. These wrongs resulted in hundreds of millions of dollars in damages to Ocular's reputation, goodwill, and standing in the business community. Moreover, these actions have exposed the Company to hundreds of millions of dollars in potential liability for violations of state and federal law.

- 2. Ocular is a biopharmaceutical company focused on the development of therapy products that treat certain eye conditions. The Company's lead product candidate is DEXTENZATM, a corticosteroid insert designed to deliver a sustained dose of dexamethasone to the ocular surface for up to thirty days for treatment of postsurgical ocular inflammation and pain, allergic conjunctivitis, and dry eye disease. Ocular has completed three Phase 3 clinical trials of DEXTENZA for treatment of postsurgical ocular inflammation and pain, two Phase 3 clinical trials of DEXTENZA for treatment of allergic conjunctivitis, and one Phase 2 clinical trial of DEXTENZA for treatment of dry eye disease. The Company has now submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") for approval to sell DEXTENZA for the treatment of postsurgical ocular pain.
- 3. As part of the FDA's review of Ocular's NDA the agency inspected Ocular's manufacturing operations from February 1, 2016 through February 5, 2016, and on February 11, 2016. Following the inspection, on February 11, 2016, the FDA issued a Form 483¹ (the "2016 Form 483") detailing the multiple manufacturing deficiencies it found related to the manufacturing of DEXTENZA. These manufacturing deficiencies included control procedures, equipment, and laboratory controls used to produce DEXTENZA.

¹ An FDA Form 483 is a document that notifies a company's management of deficient conditions observed during facility inspections. Once an FDA representative concludes his or her inspection, he or she presents the FDA Form 483 to representatives of the Company's senior management and discusses the document with them.

- 4. Ocular disclosed its receipt of the 2016 Form 483 in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2015 (the "2015 Form 10-K") filed with the SEC on March 10, 2016. In the 2015 Form 10-K, Ocular claimed to have addressed some of the deficiencies identified in the document. The Company further claimed it had provided the FDA with a corrective action plan to complete the inspection process.
- 5. On July 25 2016, the Company issued a press release announcing its receipt of a Complete Response Letter² from the FDA stating that the agency would not approve DEXTENZA until it resolved the manufacturing deficiencies the agency observed during the February 2016 inspection. The press release quoted defendant Amarpreet Sawhney ("Sawhney"), Ocular's Chief Executive Officer ("CEO") at the time, as stating that the Company had responded to all of the FDA's requests regarding the manufacturing deficiencies. Defendant Sawhney also stated that he was "optimistic" about DEXTENZA's approval prospects.
- 6. In press releases issued on August 3, 2016 and August 9, 2016, Ocular represented that its prior corrective actions had addressed all but one of the manufacturing issues identified in the 2016 Form 483. Then, on January 23, 2017, the Company announced the resubmission of its NDA for DEXTENZA.
- 7. Despite Ocular's claims that it had fixed the manufacturing issues, the FDA's second inspection of Ocular's DEXTENZA manufacturing facilities from April 24, 2017 through May 4, 2017, resulted in the agency's issuance of another FDA Form 483 (the "2017 Form 483") on May 4, 2017. The 2017 Form 483 revealed that Ocular had not corrected the deficiencies in

² An FDA Complete Response Letter communicates that the agency has completed its review of a particular application for a new or generic drug and determined not to approve the drug for marketing in its current form.

the DEXTENZA manufacturing process, including insufficient laboratory controls and written procedures. Moreover, Ocular had allowed the DEXTENZA manufacturing deficiencies to grow worse between the first and second FDA inspections. The 2017 Form 483 stated that a significant portion of DEXTENZA produced by Ocular was contaminated with particles of various substances. According to the 2017 Form 483, Ocular used contaminated DEXTENZA in clinical trials and released contaminated DEXTENZA for intended commercial use. The 2017 Form 483 also noted that "[e]mployees engaged in the manufacture, processing, packing and holding of [DEXTENZA] lack the training required to perform their assigned functions."

- 8. On May 5, 2017, Ocular issued a press release announcing its receipt of the 2017 Form 483. The press release did not disclose the details of the manufacturing deficiencies identified in the document, stating that the deficiencies merely pertained to the Company's "procedures for manufacturing processes and analytical testing." The press release misleadingly omitted the 2017 Form 483 findings regarding product contamination and insufficient employee training. That same day, Ocular filed its Quarterly Report on Form 10-Q, for the first quarter of 2017, in which the Company repeated its incomplete and misleading claim regarding the contents of the 2017 Form 483.
- 9. During an earnings conference call that took place later that day, Ocular consultant and former Executive Vice President of Regulatory, Quality, and Compliance, defendant Eric Ankerud ("Ankerud"), continued to downplay the severity of the deficiencies identified in the 2017 Form 483, claiming that the Company had the "situation under control." He stated that the DEXTENZA manufacturing process was "fully developed" and that Ocular planned to resolve the manufacturing deficiencies identified by the FDA "in a timely manner."

During the same call, defendant Sawhney claimed that the deficiencies identified in the 2017 Form 483 were "resolvable issues" and that the Company had responses for these issues.

- 10. The truth began to emerge on July 6, 2017, when "TripleGate," a hedge fund manager and contributor to the investor website *Seeking Alpha*, published an article entitled "Ocular: A Poke in the Eye." The article included copies of the 2016 and 2017 Forms 483 which TripleGate had obtained through a Freedom of Information Act ("FOIA") request. In the article, TripleGate detailed the serious nature of the manufacturing issues identified in the 2017 Form 483 and asserted that Ocular's management either did not understand the manufacturing issues raised by the FDA or had been misleading investors about these issues. The article stated:
 - ...Even a layperson reading [the 2017 Form 483] can tell that the company is having serious manufacturing issues, and their whole approach to manufacturing and patient safety is highly questionable. What's more troubling is that either management doesn't fully understand the letter, or they have been misleading investors. Both are bad.
- 11. The next day, the health and medicine reporting website *STAT* published an article entitled "Ocular Therapeutix Still Working on Manufacturing Fix for Eye Drug, with FDA Deadline Approaching." According to the article, product contamination concerns had threatened the approval prospects for Ocular's NDA for DEXTENZA. Specifically, the article discussed the agency's finding that batches of DEXTENZA had been contaminated with particulate matter, including aluminum. Moreover, the article contained a representation from defendant Sawhney that blades in a machine used to manufacture DEXTENZA were the source of the aluminum contamination. The revelations contained in the *Seeking Alpha* and *STAT* articles caused the Company to suffer a massive three-day market capitalization loss of \$107 million, from \$295 million to \$188 million.
- 12. On July 10, 2017, Ocular issued a press release announcing that it had submitted an amendment to its NDA for DEXTENZA to the FDA. According to the press release, the

amendment detailed a change in manufacturing equipment. The press release also stated that the Company had requested that the FDA extend the review period for its DEXTENZA NDA by three months. This news caused Ocular's stock price to experience a slight recovery, closing at \$7.60 per share on July 11, 2017 compared to its closing of \$6.49 per share the previous day.

- 13. Following the close of trading on July 11, 2017, Ocular issued a press release announcing the Company's receipt of another Complete Response Letter from the FDA, denying Ocular's DEXTENZA NDA. The FDA cited "deficiencies in manufacturing processes and analytical testing" as its reason for denying the Company's NDA. This announcement caused Ocular to incur a three-day market capitalization loss of nearly \$37 million, from \$220 million to \$183 million.
- 14. The Company held an earnings conference call with analyst and investors on August 8, 2017. During the call, Ocular's new CEO, Antony Mattessich, ("Mattessich"), contradicted key claims that the Company made regarding the DEXTENZA manufacturing process. For example, Mattessich explained that Ocular was performing "a fairly thorough root-cause analysis" to determine the source of the particulate matter contamination. This analysis was necessary because, as the 2017 FDA Form 483 identified, the Company was not able to consistently manufacture uncontaminated batches of DEXTENZA. If Ocular's manufacturing process was "fully developed" as defendant Ankerud previously claimed, the Company would not be struggling to properly manufacture its lead product candidate. Moreover, Mattessich referred to defendant Sawhney's claim, that the contamination resulted from blades in a machine used to manufacture DEXTENZA, as a "presumption" and an unconfirmed "suspicions."
- 15. In addition, between October 1, 2016 and December 31, 2016, while the Individual Defendants (as defined herein) were breaching their fiduciary duties, SV Life

Sciences Fund IV, L.P. and SV Life Sciences Fund IV Strategic Partners, L.P. (collectively, the "SV Entities"), investment funds controlled by defendant James Garvey ("Garvey"), sold 327,400 of their shares of Ocular stock at artificially inflated prices. The SV Entities sold these shares based on defendant Garvey's material, nonpublic information about Ocular's true business health. Based on the Company's average stock price between October 1, 2016 and December 31, 2016, the SV Entities would have realized over \$2.5 million from their unlawful sales of Ocular stock.³

- 16. The Individual Defendants' failure to correct the deficiencies in the DEXTENZA manufacturing process and their improper statements regarding these deficiencies caused the SEC to issue a subpoena against the Company on December 15, 2017. The subpoena sought documents and information regarding DEXTENZA. The subpoena also required that the Company produce related communications with the FDA, investors, and other parties.
- 17. Further, as a direct result of the Individual Defendants' unlawful course of conduct, the Company is now the subject of numerous federal securities class action lawsuits filed in the United States District Court for the District of New Jersey on behalf of investors who purchased Ocular's shares. These lawsuits were transferred to this Court on November 20, 2017.
- 18. Plaintiff now brings this action against the Individuals Defendants to repair the harm they caused with their faithless actions.

³ Between October 1, 2016 and December 31, 2016, the SV Entities sold 327,400 of their shares of Ocular stock. During that period, the Company's average closing stock price was \$7.76. Based on this average closing stock price, the SV Entities would have reaped \$2,539,584.63 in proceeds from their unlawful sales of Ocular stock.

JURISDICTION AND VENUE

- 19. Jurisdiction is conferred by 28 U.S.C. §1332. Complete diversity among the parties exists and the amount in controversy exceeds \$75,000, exclusive of interests and costs.
- 20. This Court has jurisdiction over each defendant named herein because each defendant is either a corporation that conducts business in and maintains operations in this District, or is an individual who has sufficient minimum contacts with this District to render the exercise of jurisdiction by the District courts permissible under traditional notions of fair play and substantial justice.
- 21. Venue is proper in this Court in accordance with 28 U.S.C. §1391 because: (i) Ocular maintains its principal place of business in this District; (ii) one or more of the defendants either resides in or maintains executive offices in this District; (iii) a substantial portion of the transactions and wrongs complained of herein, including the defendants' primary participation in the wrongful acts detailed herein, and aiding and abetting and conspiracy in violation of fiduciary duties owed to Ocular, occurred in this District; and (iv) defendants have received substantial compensation in this District by doing business here and engaging in numerous activities that had an effect in this District.

THE PARTIES

Plaintiff

22. Plaintiff Brian Robinson has been an Ocular stockholder since May 4, 2017, during the time of the continuing wrong complained of. The continuing wrong included: (i) the failure to correct the manufacturing deficiencies; and (ii) the issuance of improper statements. Once plaintiff became a stockholder, he has continuously been a stockholder. Plaintiff is a citizen of South Carolina.

Nominal Defendant

23. Nominal Defendant Ocular is a Delaware corporation with principal executive offices located at 15 Crosby Drive, Bedford, Massachusetts. Accordingly, Ocular is a citizen of Delaware and Massachusetts. Ocular is a biopharmaceutical company focused on the development, manufacturing, and commercialization of therapies for diseases and conditions of the eye. As of March 1, 2017, Ocular had 118 full-time employees.

Defendants

24. Defendant Sawhney is Ocular's Executive Chairman of the Board of Directors (the "Board") and has been since July 2017 and a director and has been since 2006. Defendant Sawhney cofounded the Company in 2006. Defendant Sawhney was also Ocular's President and CEO from 2006 to July 2017 and Chairman of the Board from June 2014 to July 2017. Defendant Sawhney is named as a defendant in numerous securities class action complaints that allege he violated sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). Defendant Sawhney knowingly, recklessly, or with gross negligence: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Sawhney the following compensation as an executive:

Year	Salary	Bonus	Option Awards	All Other Compensation	Total
2016	\$540,788	\$237,946	\$968,435	\$158	\$1,747,327

Defendant Sawhney is a citizen of Massachusetts.

25. Defendant Charles Warden ("Warden") is an Ocular director and has been since 2008. Defendant Warden was also Ocular's Lead Independent Director from July 2014 to at least April 2017. Defendant Warden is a member of Ocular's Audit Committee and has been since at least April 2015. Defendant Warden knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Warden the following compensation as a director:

Fiscal Year	Fees Paid in Cash	Option Awards	Total
2016	\$74,000	\$109,966	\$183,966

Defendant Warden is a citizen of California.

26. Defendant Richard L. Lindstrom ("Lindstrom") is an Ocular director and has been since 2012. Defendant Lindstrom knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Lindstrom the following compensation as a director:

		Option	
Fiscal Year	Fees Paid in Cash	Awards	Total
2016	\$48,750	\$109,966	\$158,716

Defendant Lindstrom is a citizen of Minnesota.

27. Defendant Jaswinder Chadha ("Chadha") is an Ocular director and has been since 2013. Defendant Chadha knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Chadha the following compensation as a director:

		Option	
Fiscal Year	Fees Paid in Cash	Awards	Total
2016	\$37,500	\$109,966	\$147,466

Defendant Chadha is a citizen of New Jersey.

Defendant Bruce A. Peacock ("Peacock") is an Ocular director and has been since July 2014. Defendant Peacock is the Chairman of Ocular's Audit Committee and a member of that committee and has been since at least April 2015. Defendant Peacock knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's

manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Peacock the following compensation as a director:

Figure Voor	Food Boid in Cook	Option	Total
Fiscal Year	Fees Paid in Cash	Awards	Total
2016	\$61,750	\$109,966	\$171,716

Defendant Peacock is a citizen of Pennsylvania.

29. Defendant Jeffrey S. Heier ("Heier") is an Ocular director and has been since September 2015. Defendant Heier knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Heier the following compensation as a director:

Fiscal Year	Fees Paid in Cash	Option Awards	Total
2016	\$39,674	\$109,966	\$149,640

Defendant Heier is a citizen of Massachusetts.

30. Defendant W. James O'Shea ("O'Shea") is an Ocular director and has been since November 2015. Defendant O'Shea is a member of Ocular's Audit Committee and has been since at least April 2017. Defendant O'Shea knowingly or recklessly: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about

DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant O'Shea the following compensation as a director:

		Option	
Fiscal Year	Fees Paid in Cash	Awards	Total
2016	\$41,423	\$109,966	\$151,389

Defendant O'Shea is a citizen of Massachusetts.

- 31. Defendant Ankerud is an Ocular consultant and has been since November 2017. Defendant Ankerud was also an Ocular Senior Advisor from July 2017 to October 2017; Executive Vice President, Regulatory, Quality and Compliance from February 2016 to July 2017; and Executive Vice President, Clinical, Regulatory and Quality from 2007 to January 2016. Defendant Ankerud is named as a defendant in numerous securities class action complaints that allege he violated sections 10(b) and 20(a) of the Exchange Act. Defendant Ankerud knowingly, recklessly, or with gross negligence: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Defendant Ankerud is a citizen of New Hampshire.
- 32. Defendant Garvey was an Ocular director from 2010 to June 2017. Defendant Garvey was also a member of Ocular's Audit Committee from at least April 2015 to June 2017. As a member of the investment committee of the SV Entities, defendant Garvey may be deemed to share voting, dispositive, and investment power over the Ocular shares held of record by the SV Entities. Defendant Garvey knowingly or recklessly: (i) caused or allowed Ocular to pursue

FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Moreover, while in possession of material, nonpublic information concerning Ocular's true business health, defendant Garvey caused the SV Entities to sell 327,400 of their shares of Ocular stock. Ocular paid defendant Garvey the following compensation as a director:

		Option	
Fiscal Year	Fees Paid in Cash	Awards	Total
2016	\$56,500	\$109,966	\$166,466

Defendant Garvey is a citizen of Florida.

33. Defendant George Migausky ("Migausky") was Ocular's interim Chief Financial Officer from April 2017 to September 2017. Defendant Migausky is named as a defendant in numerous securities class action complaints that allege he violated sections 10(b) and 20(a) of the Exchange Act. Defendant Migausky knowingly, recklessly, or with gross negligence: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Defendant Migausky is a citizen of Massachusetts.

34. Defendant Smith was an Ocular consultant from March 2017 to May 2017 and Chief Financial Officer from March 2014 to March 2017. Defendant Smith knowingly, recklessly, or with gross negligence: (i) caused or allowed Ocular to pursue FDA approval for DEXTENZA without correcting significant deficiencies in the DEXTENZA manufacturing process; (ii) caused or allowed the Company to expend substantial resources manufacturing DEXTENZA despite having knowledge of these deficiencies; and (iii) caused or allowed the Company to make improper statements about DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Ocular paid defendant Smith the following compensation as an executive:

				All Other	
Year	Salary	Bonus	Option Awards	Compensation	Total
2016	\$345,205	\$113,918	\$289,506	\$188	\$748,817

Defendant Smith is a citizen of New Hampshire.

35. The defendants identified in ¶¶24, 31, 33, and 34 are referred to herein as the "Officer Defendants." The defendants identified in ¶¶24-30, and 32 are referred to herein as the "Director Defendants." The defendants identified in ¶¶25, 28, 30, and 32 are referred to herein as the "Audit Committee Defendants." Collectively, the defendants identified in ¶¶24-34 are referred to herein as the "Individual Defendants."

DUTIES OF THE INDIVIDUAL DEFENDANTS

Fiduciary Duties

36. By reason of their positions as officers and directors of the Company, each of the Individual Defendants owed and owe Ocular and its stockholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to control and manage Ocular in a fair, just, honest, and equitable manner. The Individual Defendants were

and are required to act in furtherance of the best interests of Ocular and not in furtherance of their personal interest or benefit.

- 37. To discharge their duties, the officers and directors of Ocular were required to exercise reasonable and prudent supervision over the management, policies, practices, and controls of the financial affairs of the Company. By virtue of such duties, the officers and directors of Ocular were required to, among other things:
- (a) accurately guide the Company's stockholders and the public when speaking about Ocular's business endeavors, including DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies;
- (b) detect and correct deficiencies in the manufacturing processes for the Company's drug product candidates, including DEXTENZA;
- (c) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable laws, rules, and regulations;
- (d) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and refraining from engaging in deceptive or fraudulent conduct;
- (e) refrain from selling, or causing entities with which they are affiliated from selling, Ocular stock on the basis of nonpublic insider information;
- (f) ensure processes were in place for maintaining the integrity and reputation of the Company and reinforcing a culture of ethics, compliance, and appropriate risk management;

- (g) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;
- (h) remain informed as to how Ocular conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with applicable laws; and
- (i) truthfully and accurately guide investors and analysts as to the business operations of the Company at any given time.

Breaches of Duties

- 38. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as officers and directors of Ocular, the absence of good faith on their part, and a reckless disregard for their duties to the Company that the Individual Defendants were aware or reckless in not being aware posed a risk of serious injury to the Company.
- 39. The Individual Defendants breached their duty of loyalty and good faith by allowing defendants to cause, or by themselves causing, the Company to make improper statements to the public and Ocular's stockholders and engage in improper practices that wasted the Company's assets, and caused Ocular to incur substantial damage. Moreover, defendant Garvey abused his duty of loyalty by causing the SV Entities to sell their shares of Ocular stock based on nonpublic information about the Company's financial health.
- 40. The Individual Defendants, because of their positions of control and authority as officers and/or directors of Ocular, were able to and did, directly or indirectly, exercise control

over the wrongful acts complained of herein. The Individual Defendants also failed to prevent the other Individual Defendants from taking such illegal actions. As a result, and in addition to the damage the Company has already incurred, Ocular has expended, and will continue to expend, significant sums of money.

Additional Duties of the Audit Committee Defendants

41. In addition to these duties, under its Charter, the Audit Committee Defendants, defendants Warden, Peacock, O'Shea, and Garvey, owed specific duties to Ocular to assist the Board in overseeing "the Company's internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics." The Audit Committee Charter also required the Audit Committee Defendants to discuss the Company's policies regarding risk assessment, management, and exposure. According to the Audit Committee Charter:

Oversight. The Audit Committee shall coordinate the Board's oversight of the Company's internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics. The Audit Committee shall receive and review the reports of the Chief Executive Officer and the Chief Financial Officer required by Rule 13a-14 under the Exchange Act.

<u>Risk Management</u>. The Audit Committee shall discuss the Company's policies with respect to risk assessment and risk management, including guidelines and policies to govern the process by which the Company's exposure to risk is handled.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

42. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their common plan or design. In addition to the wrongful conduct herein alleged as giving rise to primary liability, the Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

- 43. During all times relevant hereto, the Individual Defendants, collectively and individually, initiated a course of conduct that was designed to and did: (i) deceive the investing public, including stockholders of Ocular, regarding the Individual Defendants' management of Ocular's operations and the approval prospects for the Company's DEXTENZA NDA; and (ii) facilitate the SV Entities' illicit sale of their Ocular shares while in possession of material nonpublic Company information provided by defendant Garvey.
- 44. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants, collectively and individually, took the actions set forth herein.
- 45. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants caused the Company to issue improper financial statements.
- 46. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to disguise the Individual Defendants' violations of law, breaches of fiduciary duty, waste of corporate assets, and unjust enrichment; and to conceal adverse information concerning the Company's operations, financial condition, and future business prospects.
- 47. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to purposefully or recklessly release improper statements. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.
- 48. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the

commission of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted in the accomplishment of that wrongdoing, and was aware of his overall contribution to and furtherance of the wrongdoing.

FACTUAL BACKGROUND

- 49. Ocular is a biopharmaceutical company focused on the development and commercialization of therapies that treat various eye conditions. These therapies utilize the Company's proprietary hydrogel technology which allows for the sustained release of pharmaceuticals to targeted ocular tissues. Currently, the only product that Ocular markets is ReSure Sealant, an ocular sealant that uses hydrogel technology to seal clear corneal incisions following cataract surgery. ReSure Sealant brings in less than \$500,000 per quarter in revenue.
- 50. The Company's lead product candidate is called DEXTENZA. DEXTENZA is a corticosteroid intracanalicular insert placed through a natural opening in the eye lid called the punctum, and into the canaliculus. Once in place, DEXTENZA is designed to use Ocular's hydrogel technology to deliver a tapered dose of dexamethasone to the ocular surface for up to thirty days for treatment of postsurgical ocular inflammation and pain, allergic conjunctivitis, and dry eye disease. After this treatment is complete, DEXTENZA is intended to exit the nasolacrimal duct without the need for removal.
- 51. In order to sell DEXTENZA in the United States, Ocular must first receive approval from the FDA. The FDA approval process is long, arduous, and expensive. It requires lengthy, expensive, and time-consuming tests and trials. The further a company proceeds through the testing process, the larger, longer, and more expensive the trials become.
- 52. The first stage in the process is a Phase 1 trial in which a company tests a medication's safety, appropriate dosage, and side effects on a small group of patients. This is

followed by a Phase 2 trial which uses a larger group of patients to test a drug's effectiveness and side effects. Phase 3, normally the final phase in the approval process, uses the largest group of patients. Phase 3 clinical trials compare the medication to other commonly used treatments and provide further information on the medication's safety and efficacy. According to FDA guidelines and pharmaceutical standards, these trials usually take several years to complete to determine the long-term effects of a medication on patients. If a company has evidence from its early tests, preclinical, and clinical research that a drug is safe and effective for its intended use, the company can apply to receive FDA approval for the drug by filing an NDA with the FDA.

53. Ocular has completed three Phase 3 clinical trials of DEXTENZA for treatment of postsurgical ocular inflammation and pain, two Phase 3 clinical trials of DEXTENZA for treatment of allergic conjunctivitis, and one Phase 2 clinical trial of DEXTENZA for treatment of dry eye disease. The Company has now submitted a NDA to the FDA for approval to sell DEXTENZA for the treatment of postsurgical ocular pain. Ocular has supported this NDA with data from two Phase 3 clinical trials and a prior Phase 2 clinical trial of DEXTENZA for postsurgical ocular inflammation and pain.

THE INDIVIDUAL DEFENDANTS MAKE A SERIES OF IMPROPER STATEMENTS AS THEY FAIL TO CORRECT OCULAR'S MANUFACTURING DEFICIENCIES

54. The Individual Defendants repeatedly misled the public regarding deficiencies in the DEXTENZA manufacturing process. The FDA inspected Ocular's manufacturing facilities and alerted the Company to serious deficiencies in the DEXTENZA manufacturing process on two separate occasions. However, rather than correcting these deficiencies, the Individual Defendants allowed the deficiencies to grow worse and caused the Company to make multiple improper statements regarding DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies.

- 55. The FDA inspected Ocular's manufacturing operations from February 1, 2016 through February 5, 2016, and on February 11, 2016 as part of its review of Ocular's NDA for DEXTENZA. Following the inspection, on February 11, 2016, the FDA issued the 2016 Form 483 detailing the manufacturing problems it observed regarding the DEXTENZA manufacturing process. These problems included deficiencies in Ocular's control procedures, equipment, and laboratory controls.
- 56. On March 10, 2016, Ocular filed it 2015 Form 10-K with the SEC. It was signed by defendants Sawhney, Smith, Chadha, Garvey, Heier, Lindstrom, O'Shea, Peacock, and Warden. The 2015 Form 10-K detailed the Company's financial results for the 2015 fiscal year. It further disclosed the occurrence of the FDA inspection and the Company's receipt of the 2016 Form 483. The Company claimed, in the 2015 Form 10-K, that it had addressed some of these deficiencies and provided the FDA with a corrective action plan to complete the inspection process. Ocular's 2015 Form 10-K stated:

In addition, in February 2016, as part of the ongoing review of our NDA for DEXTENZA, the FDA conducted a pre-NDA approval inspection of our manufacturing operations. As a result of this inspection, we received an FDA Form 483 containing inspectional observations focused on process controls, analytical testing and physical security procedures related to manufacture of our drug product for stability and commercial production purposes. We addressed some observations before the inspection was closed and have responded to the FDA with a corrective action plan to complete the inspection process.

57. On July 25, 2016, the Company issued a press release announcing its receipt of a Complete Response Letter from the FDA regarding DEXTENZA. According to the press release, the FDA would not approve DEXTENZA until Ocular resolved the manufacturing deficiencies the agency observed during its inspection of its facilities. The press release stated:

BEDFORD, Mass, July 25, 2016 (BUSINESS WIRE): Ocular Therapeutix, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development and commercialization of innovative therapies for diseases and conditions of the eye, today announced that it received a Complete Response Letter (CRL) from the

U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for DEXTENZATM (dexamethasone insert) 0.4 mg, for intracanalicular use in the treatment of ocular pain occurring after ophthalmic surgery.

The concerns raised by the FDA pertain to deficiencies in manufacturing process and controls identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility. The FDA's letter did not provide any details as to which manufacturing deficiencies identified during the facility inspection remain open since the last response submitted by the Company.

Satisfactory resolution of the manufacturing deficiencies identified during the FDA facility inspection is required before the NDA may be approved. The FDA's letter did not identify any efficacy or safety concerns with respect to the clinical data provided in the NDA nor any need for additional clinical trials for the approval of the NDA.

58. The press release also quoted defendant Sawhney as stating that Ocular had previously responded to all of the FDA's requests regarding the manufacturing deficiencies, and that the Company was "optimistic" about DEXTENZA's approval prospects. The press release stated:

"We have previously responded to all requests in an effort to address the manufacturing items raised by the FDA during the application process, and we await completion of the review," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "Importantly, there were no clinical issues identified in the CRL pertaining to efficacy or safety related to the post-surgical pain indication. Labeling discussions with the FDA are ongoing. We remain optimistic that DEXTENZA will be approved once these open manufacturing items are closed. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and are committed to bringing DEXTENZA to market as rapidly as possible."

59. On August 3, 2016, the Company issued a press release claiming that Ocular's prior corrective actions had addressed all but one of the manufacturing issues identified in the 2016 Form 483. The press release stated:

Recently, the FDA issued a letter to Ocular Therapeutix noting that corrective actions detailed in its responses as a whole appear to address the ten inspectional observations raised in the Form FDA 483 with one exception which relates to the proposed process for identity testing of an incoming inert gas component used in the manufacturing process. In this letter, the FDA also requested that the Company provide evidence (e.g., a final report) when migration

to automatic integration of analytical testing is complete, which is anticipated during the third quarter of 2016.

"We are working closely with the FDA to address the one remaining item and are planning for a resubmission to our NDA as soon as possible," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "We remain committed to bringing DEXTENZA to market as rapidly as possible."

60. Ocular repeated its claim that it was working to resolve one remaining manufacturing issue in its August 9, 2016 earnings press release. The press release stated:

"The second half of 2016 will be a busy time for Ocular Therapeutix as we prepare to initiate the first of two planned Phase 3 clinical trials with OTX-TP for the treatment of glaucoma and ocular hypertension during the third quarter," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "Regarding our NDA for DEXTENZA for the treatment of post-surgical ocular pain, labeling discussions with the FDA are ongoing, and as we just announced, we are working to resolve the one remaining open manufacturing observation identified by the FDA in connection with their facility inspection. We will continue to work collaboratively with the FDA so they can finalize their review of our NDA, and we remain committed to bringing DEXTENZA to market."

61. On January 23, 2017, the Company issued a press release announcing the resubmission of its NDA for DEXTENZA. The press release stated:

"Following productive discussions with the FDA, we are pleased to announce the resubmission of our NDA for DEXTENZA for the treatment of ocular pain occurring after ophthalmic surgery," said Amar Sawhney, Ph.D., President, Chief Executive Officer and Chairman. "If DEXTENZA is approved, we believe that its ability to provide a complete course of steroid therapy with one-time administration in the post-surgical setting will be extremely attractive for both ophthalmologists and patients. We continue to build our commercial organization and infrastructure in preparation for the earliest possible launch of DEXTENZA, subject to marketing approval."

62. The Individual Defendants, however, did not address the Company's manufacturing and control problems. From April 24, 2017 through May 4, 2017, the FDA inspected Ocular's manufacturing facilities for a second time. During this inspection, the agency found repeat deficiencies including insufficient laboratory controls and written procedures. In addition, the Individual Defendants allowed the DEXTENZA manufacturing problems to worsen

between the first and second FDA inspections. The FDA found new, more serious manufacturing deficiencies during its second inspection of Ocular's facilities. These deficiencies included product contamination issues and improperly trained employees. The FDA sent the Company the 2017 Form 483 detailing these and other deficiencies.

63. On May 5, 2017, Ocular issued a press release announcing its first quarter earnings for fiscal 2017. The press release also announced receipt of the 2017 Form 483 following the FDA's reinspection of Ocular's DEXTENZA manufacturing facilities. According to the press release, the 2017 Form 483 identified deficiencies concerning the Company's "procedures for manufacturing processes and analytical testing." The Company, however, did not attach the 2017 Form 483 or disclose its true contents. The press release stated:

A New Drug Application (NDA) for DEXTENZA (dexamethasone insert) 0.4mg for intracanalicular use is currently under review by the U.S. Food and Drug Administration (FDA) for the treatment of ocular pain following ophthalmic surgery. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of July 19, 2017 for a decision regarding the potential approval of DEXTENZA. Following a re-inspection of manufacturing operations by the FDA which was completed earlier this week, Ocular Therapeutix received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing, related to manufacture of drug product for commercial production. The Company plans to evaluate and respond to the FDA within 15 days with corrective action plans to complete the inspection process. Adequate resolution of the outstanding Form 483 inspectional observations is a prerequisite to the approval of the NDA for DEXTENZA.

64. That same day, Ocular filed its Quarterly Report on Form 10-Q with the SEC, signed by defendant Migausky, in which it repeated this claim multiple times. The Form 10-Q stated:

Following a re-inspection of manufacturing operations by the FDA which was completed in early May 2017, we received an FDA Form 483 containing inspectional observations focused on procedures for manufacturing processes and analytical testing related to manufacture of drug product for commercial production.

65. During an earnings conference call that took place later that day with analysts and investors, defendant Ankerud downplayed the severity of the deficiencies identified in the 2017 Form 483 and claimed that the Company had the "situation under control." He also represented that the Company expected to resolve the deficiencies "in a timely manner," and that the DEXTENZA manufacturing process was "fully developed." Defendant Ankerud stated:

Good morning, Ken, thanks for the question. FDA completed their re-inspection of our facility as part of the NDA review late yesterday afternoon. As Amar mentioned 483 was issued.

We were pleased during the re-inspection that the FDA investigator was able to confirm our corrective action plan from prior observations and indicated that there was no further follow-up necessary to close out those issues. This was a new investigator, not the same investigator from prior inspections, and their primary focus in the 483 relates to a particulate matter issue as part of our manufacturing process. The issue relates primarily to completion of an investigation that we have underway in regard to the particulate matter, solidifying specifications for in-process 100% visual inspection of our inserts as well as enhancing our operator training.

We feel quite comfortable that we have the situation under control. And we are preparing responses to the 483 as of this morning in anticipation of responding within 15 calendar days to the agency. In addition to the particulate matter issue FDA raised a couple of observations in regard to analytical method testing to be completed as well as some other issue related to quality oversight of batch records.

So in summary, we believe that each of the observations raised by FDA during this continuous improvement review of **our fully developed manufacturing process** are handlable and will be resolved in our response to FDA. We are also pleased that the collaborative nature of our NDA review has continued between the various offices of FDA, and we are marching toward that PDUFA date and expect that we can resolve the 483 issues in a timely manner.

* * *

And during this re-inspection the new investigator is responsible for confirming that we have implemented what was said in our responses. And the investigator went through each of our responses and confirmed that we had properly and appropriately implemented those actions. So I think that's a strong sign that the manufacturing process has moved forward significantly and is in a fully developed mode.

66. During the same earnings call, defendant Sawhney responded to a question from a Morgan Stanley analyst by representing that the deficiencies identified in the 2017 Form 483 were "resolvable issues" and that the Individual Defendants had responses for these issues. The exchange occurred as follows:

[Analyst]: Is there anything in their observations that you think could delay the action date specifically?

[Defendant Sawhney]: Nothing that we can currently see.... The question is what are the nature of the issues in the 483.

We think these are resolvable issues. And we have responses some already prepared and some being prepared to address them in a timely fashion.

67. However, as Ocular investors and the public would soon discover, the DEXTENZA manufacturing deficiencies identified in the 2016 and 2017 Forms 483 were far more significant than the Individual Defendants had previously represented, and the Individual Defendants had failed to correct these deficiencies.

THE TRUTH BEGINS TO EMERGE

68. Ocular investors began to learn the extent of the Company's DEXTENZA manufacturing problems on July 6, 2017, when TripleGate, a hedge fund manager and contributor to the investor website *Seeking Alpha*, posted an article to the website entitled *Ocular: A Poke in the Eye*. TripleGate obtained copies of the 2016 and 2017 Forms 483 through a FOIA request and made them available to the public for the first time by including them in the article. The 2017 Form 483 contained the shocking finding that Ocular had not seen to it that the Company's manufacturing employees were properly trained. According to the 2017 Form 483, "Employees engaged in the manufacture, processing, packing and holding of [DEXTENZA] lack the training required to perform their assigned functions." The 2017 Form 483 also revealed severe deficiencies in the most basic aspects of the DEXTENZA manufacturing controls. For

instance, the fourth FDA observation listed in the 2017 Form 483 states "The responsibilities and procedures applicable to the quality control unit are not in writing."

69. TripleGate's article raised concerns that Ocular had misled the public regarding the content of the 2016 and 2017 Forms 483, and the sufficiency of the Company's efforts to resolve the deficiencies identified in the documents. For example, Ocular repeatedly represented that it had resolved all but one of the deficiencies identified in the 2016 Form 483. However, the 2017 Form 483 revealed the presence of *multiple* repeat deficiencies and the discovery of even worse deficiencies. The article stated:

Now, let's look at reality:

First, OCUL has REPEAT observations. Not only did they not resolve prior issues, but have committed worse transgressions. Here is a copy of the first 483 [sic].

Observation 6 reads: "Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity."

Observation 5 of the second 483 reads: "Laboratory controls do not include the establishment of scientifically sound and appropriate specifications and test procedures designed to assure that drug products conform to appropriate standards of identity, strength, quality and purity." *Sounds familiar?*

Observation 3 of the second 483 reads: "There are no written procedures for production and process controls designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Specifically, your firm lacks documentation to show that your product can consistently meet specifications as you have not systemically evaluated the [redacted] lots manufactured from FEB2016 to present, of which [redacted] failed specification and were disposed of in-process"

In plain English, this means, OCUL still doesn't know to make their product consistently. How does OCUL deal with instances when product doesn't meet specifications? They have been discarding bad manufacturing lots without investigation.

70. The article shows that contrary to defendant Ankerud's claim that the DEXTENZA manufacturing process was "fully developed," Ocular did not even know how to consistently make its product. The 2017 Form 483 further revealed that Ocular had used contaminated DEXTENZA in clinical trials and had even released contaminated DEXTENZA for intended commercial use. The article stated:

Second, OCUL has characterized their manufacturing as "*in a fully developed mode.*" Well, Observation 1 of the second 483 reads: "Particulate matter has been noted in 10/23 lots (intended use clinical, R&D, stability, etc.) manufactured from FEB2016 to date. The remaining [redacted] lots were scrapped prior to the visual inspection therefore their particulate status remains unknown."

In plain English, this means that more than 50% of lots manufactured by OCUL contain bad product. That leaves plenty of room for additional development. Sometimes, OCUL has had to discard entire lots because they were out of spec!!

Third, if OCUL only discarded bad product without investigation, that would be a bad thing. But in fact, they have been using bad product in clinical trials and have released some into their commercial supply!

Observation 1 continues: "Particulates were not logged as product defects prior to FEB2016, therefore lots released prior to that date, such as clinical trial lots [redacted], released [redacted]respectively and used in human clinical trials are unknown with respect to particulate status."

Observation 2 reads: "The following batches were released without an understanding of the defects present, more specifically, particulate matter of unknown origin and composition at the time of release:all three lots were released for intended commercial use on 12JAN2017 without critical defect limits"

71. These revelations demonstrated that Ocular's DEXTENZA manufacturing deficiencies were far more serious than the Company represented in its May 5, 2017 Form 10-Q. The Company repeatedly claimed, in the Form 10-Q, that the manufacturing deficiencies identified in the 2017 Form 483 pertained to "procedures for manufacturing processes and analytical testing." However, the Form 10-Q failed to disclose the 2017 Form 483 findings that the Company produced significant quantities of contaminated DEXTENZA, used contaminated

DEXTENZA in clinical trials, and released contaminated DEXTENZA for intended commercial use. Moreover, the Form 10-Q failed to disclose the 2017 Form 483 finding that the Company had not properly trained Ocular's manufacturing employees to do their jobs.

72. Based on the nature and magnitude of the deficiencies identified in the 2017 Form 483, TripleGate concluded that it may take years for Ocular to remedy the DEXTENZA manufacturing process in a way that allows the drug to be mass produced. However, TripleGate noted that it is not yet clear whether mass production of DEXTENZA is even possible. The article stated:

OCUL believes that their manufacturing is "fully developed" and remaining issues can be resolved quickly. The reality is, IF Dextenza is possible to manufacture on a mass scale, something which hasn't been done before, OCUL needs to revamp their entire process from the ground up, which can take years to do. They need to use the proper scientific tools and procedures. (Observation 5 of the second 483 says that the scales OCUL has been using aren't sensitive enough to weigh the "full range of materials")

73. The next day, the health and medicine reporting website *STAT* posted an article entitled "Ocular Theraputix Still Working on Manufacturing Fix for Eye Drug, with FDA Deadline Approaching." The article stated that product contamination concerns could cause the FDA to reject Ocular's NDA for DEXTENZA. In particular, the article discussed the agency's finding that batches of DEXTENZA had been contaminated with various particles, including aluminum. According to the article, the FDA cited the Company for failing to identify the source of the contamination and for not having implemented a procedure to detect contaminated product before it reached patients. The article also contained defendant Sawhney's claim that blades in a machine used during the DEXTENZA manufacturing process were the source of the aluminum contamination. All of these revelations caused Ocular to incur a three-day market capitalization loss of \$107 million.

74. On July 11, 2017, Ocular issued a press release announcing its receipt of another Complete Response Letter from the FDA, denying the Company's DEXTENZA NDA. According to the press release, the FDA cited "deficiencies in manufacturing processes and analytical testing" as the agency's reason for denying the application. The press release stated:

BEDFORD, Mass.--(BUSINESS WIRE)--Jul. 11, 2017-- Ocular TherapeutixTM, Inc. (NASDAQ:OCUL), a biopharmaceutical company focused on the development, manufacturing and commercialization of innovative therapies for diseases and conditions of the eye, announced today that it received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA), regarding its resubmission of a New Drug Application (NDA) for DEXTENZATM (dexamethasone insert) 0.4mg for the treatment of ocular pain following ophthalmic surgery. *The CRL states that the FDA has determined that it cannot approve the NDA in its present form.*

The CRL from the FDA refers to deficiencies in manufacturing processes and analytical testing related to manufacture of drug product for commercial production identified during a pre-NDA approval inspection of the Ocular Therapeutix manufacturing facility that was completed in May 2017. As previously announced on July 10, 2017, the Company submitted a response intended to close out all inspectional observations included in the Form FDA-483 issued in May 2017. The Company also submitted details of a manufacturing equipment change on July 10, 2017 as an amendment to the NDA resubmission and requested that this be considered a major amendment that would extend the target action date under the Prescription Drug User Fee Act (PDUFA).

- 75. This announcement revealed that Ocular's failure to correct its DEXTENZA manufacturing deficiencies had caused the FDA to reject its DEXTENZA NDA for a second time. The disclosure caused Ocular to incur a three-day market capitalization loss of nearly \$37 million.
- 76. On August 8, 2017, the Company held an earnings conference call with analysts and investors to discuss the financial results for the second quarter of 2017. Ocular's new CEO, Mattessich, contradicted key statements that Ocular officers had made regarding the DEXTENZA manufacturing process. Contrary to defendant Ankerud's claim that the DEXTENZA manufacturing process was "fully developed," Mattessich stated that Ocular was

performing "a fairly thorough root-cause analysis" to determine the source of the particulate matter contamination. This analysis was necessary because, as the 2017 FDA Form 483 noted, Ocular was not able to consistently manufacture uncontaminated batches of DEXTENZA. If the Company's manufacturing process was in a "fully developed mode," as defendant Ankerud previously represented, Ocular would not be struggling to properly manufacture its lead product candidate. Mattessich referred to defendant Sawhney's claim, that the particulate matter contamination resulted from blades in a machine used to manufacture DEXTENZA, as a "presumption" and an unconfirmed "suspicion."

- 77. Ocular's failure to resolve significant deficiencies in the DEXTENZA manufacturing process and improper statements regarding these deficiencies caused the SEC to initiate an investigation of the Company. On December 22, 2017, the Company issued a press release announcing that the SEC had issued a subpoena against the Company a week prior. According to the press release, the subpoena sought documents and information regarding DEXTENZA as well as related communications with the FDA, investors, and other parties.
- 78. Additionally, as a direct result of the Individual Defendants' unlawful course of conduct, several Ocular investors have filed federal securities lawsuits against the Company.

INSIDER SALES BY DEFENDANT GARVEY CONTROLLED FUNDS

79. Rather than providing the market with correct information, defendant Garvey used his knowledge of Ocular's material, nonpublic information to cause the SV Entities to sell their holdings of Ocular stock while the Company's stock price was artificially inflated. The Company's April 20, 2017 Proxy Statement disclosed that defendant Garvey owned beneficial Company stock consisting of shares of Ocular stock held by the SV Entities. The SV Entities are controlled by an entity called SVLSF IV, LLC. SVLSF IV, LLC is the general partner of an

entity called SV Life Sciences Fund IV (GP), LP which serves as the general partner of the SV Entities.

- 80. Defendant Garvey is a member of the SVLSF IV, LLC investment committee. This position allows him to influence the SV Entities' stock sales. Moreover, as a director of Ocular, defendant Garvey was privy to material, nonpublic information about the Company's true business health.
- 81. Between October 1, 2016 and December 31, 2016, while the Individual Defendants were misleading the public about their response to the DEXTENZA manufacturing deficiencies identified in the 2016 Form 483, defendant Garvey caused the SV Entities to sell 327,400 of their shares of Ocular stock. Data regarding the proceeds the SV Entities reaped from these sales is not currently available. However, during the period in which these sales took place, the Company's average closing stock price was \$7.76 per share. Based on this average closing stock price, the SV Entities would have reaped over \$2.5 million from their illicit sales of Company stock.

DAMAGES TO OCULAR

- 82. As a result of the Individual Defendants' improprieties, Ocular failed to correct significant deficiencies in the DEXTENZA manufacturing process and disseminated improper, public statements concerning DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. This misconduct has devastated Ocular's credibility as reflected by the Company's almost \$243 million, or 68.8%, market capitalization loss.
- 83. Ocular's performance issues also damaged its reputation within the business community and in the capital markets. In addition to price, Ocular's current and potential

customers consider a company's ability to detect and correct manufacturing deficiencies and disclose accurate information to the public. The Company requires a substantial amount of cash to complete the clinical development and commercialization of its product candidates. Ocular's ability to raise equity capital or debt on favorable terms in the future is now impaired. In addition, the Company stands to incur higher marginal costs of capital and debt because the improper statements and misleading projections disseminated by the Individual Defendants have materially increased the perceived risks of investing in and lending money to Ocular. Moreover, defendant Garvey damaged the Company by causing the SV Entities to sell 327,400 of their shares of Ocular stock based on his knowledge of material, nonpublic information about the Company.

- 84. Further, as a direct and proximate result of the Individual Defendants' actions, Ocular has expended, and will continue to expend, significant sums of money. Such expenditures include, but are not limited to:
- (a) costs incurred from defending and paying any settlement or judgment in the class actions for violations of federal securities laws;
- (b) costs incurred from responding to and paying any penalties issued as a result of the SEC's investigation of Ocular;
- (c) costs incurred from the misappropriation of Company information by defendant Garvey for the purpose of causing the SV Entities to sell Ocular common stock at artificially inflated prices;
- (d) costs incurred from manufacturing significant quantities of contaminated DEXTENZA due to the Individual Defendants' failure to correct serious deficiencies in the DEXTENZA manufacturing process; and

(e) costs incurred from compensation and benefits paid to the defendants who have breached their duties to Ocular.

DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS

- 85. Plaintiff brings this action derivatively in the right and for the benefit of Ocular to redress injuries suffered, and to be suffered, by Ocular as a direct result of breaches of fiduciary duty, waste of corporate assets, and unjust enrichment, as well as the aiding and abetting thereof, by the Individual Defendants. Ocular is named as a nominal defendant solely in a derivative capacity. This is not a collusive action to confer jurisdiction on this Court that it would not otherwise have.
- 86. Plaintiff will adequately and fairly represent the interests of Ocular in enforcing and prosecuting its rights.
- 87. Plaintiff has been an Ocular stockholder since May 4, 2017, during the time of the continuing wrong complained of. The continuing wrong included: (i) the failure to correct the manufacturing deficiencies; and (ii) the issuance of improper statements. Once plaintiff became a stockholder, he has continuously been a stockholder.
- 88. The current Board of Ocular consists of the following eight individuals: defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea and nondefendant Antony Mattessich. Plaintiff has not made any demand on the present Board to institute this action because such a demand would be a futile, wasteful, and useless act, as set forth below.

Demand Is Excused Because Defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea Face a Substantial Likelihood of Liability for Their Misconduct

89. Defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea breached their fiduciary duties of loyalty by failing to correct significant deficiencies in the

manufacturing process for the Company's lead product, DEXTENZA. These defendants failed to address the deficiencies identified in the 2016 Form 483 as evidenced by the presence of repeat deficiencies in the 2017 Form 483. Moreover, following the Company's receipt of the 2016 Form 483, defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea allowed the quality of the DEXTENZA manufacturing process to deteriorate further. The 2017 Form 483 listed even worse deficiencies than the 2016 Form 483, including product contamination issues and improperly trained employees. Defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea face a substantial likelihood of liability for breaching their fiduciary duties of loyalty. As a result, any demand made on these defendants is futile.

- 90. As alleged above, defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea breached their fiduciary duties of loyalty by making improper statements regarding DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies. Defendants Sawhney, Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea made these improper statements in the Company's 2015 Form 10-K. Additionally, defendant Sawhney made improper statements regarding these subjects in Company press releases and during a conferences call with investors and analysts. Demand on defendant Sawhney is futile because he faces a substantial likelihood of liability for breaching his duty of loyalty.
- 91. Defendants Warden, Peacock, and O'Shea, as members of the Audit Committee, allowed Ocular to issue an earnings press release and submit Forms 10-K and 10-Q filings that contained improper statements. Under the Audit Committee Charter, defendants Warden, Peacock, and O'Shea had a duty to assist the Board in overseeing "the Company's internal control

over financial reporting, disclosure controls and procedures and code of business conduct and ethics." Nonetheless, these defendants breached this duty by allowing Ocular to issue the May 5, 2017 earnings press release and file the May 5, 2017 Form 10-Q which contained incomplete, improper statements regarding the manufacturing deficiencies identified in the 2017 Form 483. Defendants Warden, Peacock, and O'Shea also breached this duty by allowing the Company to file the 2015 Form 10-K which misleadingly claimed that Ocular had addressed some of the manufacturing deficiencies identified in the 2016 Form 483.

- 92. The Audit Committee Charter also required defendants Warden, Peacock, and O'Shea to discuss the Company's policies regarding risk assessment, management, and exposure. However, these defendants failed to uphold this duty as evidenced by severe deficiencies in the Company's DEXTENZA manufacturing process, including product contamination, improperly trained employees, and insufficient controls. Their failure to properly discuss polices designed to prevent such risks resulted in the FDA rejecting the NDA for DEXTENZA two times. For this reason, defendants Peacock, Warden, and O'Shea face a substantial likelihood of liability for breaching their fiduciary duties of loyalty. Any demand made on these defendants is futile.
- 93. Director Defendants Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea and nondefendant director Mattessich lack independence from defendant Sawhney, who faces a substantial likelihood of liability, because defendant Sawhney dominates the Board. As cofounder of Ocular, and the Company's former CEO, defendant Sawhney has a significant amount of influence over the Company and its directors. He retained this influence after stepping down from his position as Company CEO in July 2017 by transitioning to the role of Executive Chairman of the Board.

- 94. Because defendant Sawhney founded Ocular and several other companies, defendants Peacock and Warden will not bring a lawsuit against him, despite the fact that he faces a substantial likelihood of liability. Defendant Peacock is a partner with a venture capital firm called SV Health Investors. Defendant Warden is managing director of a venture capital firm called Versant Ventures ("Versant"). SV Health Investors and Versant would incur significant financial and reputational damage if defendants Peacock and Warden agreed to bring a lawsuit against defendant Sawhney. If these defendants agreed to bring an action defendant Sawhney, defendant Sawhney and founders of other companies may not present SV Health Investors and Versant with future investment opportunities.
- 95. In addition, SV Health Investors and Versant have a long history of investing in companies in which defendant Sawhney founded or is affiliated with. In particular:
- (a) Versant invested in Augmenix, Inc.'s ("Augmenix") seed round of funding in 2008 and again in October 2009. Augmenix is a biopharmaceutical company focused on the development and commercialization of radiation oncology products using its proprietary hydrogel technology. Defendant Sawhney founded Augmenix in 2008 and serves as a director and Chairman of the Board of Directors for Augmenix. He also served as Augmenix's CEO from 2008 to 2014.
- (b) SV Health Investors invested in Confluent Surgical, Inc. ("Confluent Surgical") in at least March 2005. Confluent Surgical was a manufacturer and seller of dural

⁴SV Health Investors is a private equity and venture capital firm that invests in the healthcare sector and at all stages of company development, and manages over \$2 billion in capital across seven private healthcare funds.

⁵ Versant is a venture capital firm that invests in the healthcare sector and at all stages of company development.

repair, surgical sealants and adhesion barrier products.⁶ Defendant Sawhney founded this company in 1998 and served as its President and CEO from that year until 2006.

- (c) In December 2008, Versant and Incept, LLC ("Incept")⁷, a company defendant Sawhney cofounded in 1998, both participated in the Series A financing round for HotSpur Technologies, Inc., a developer of catheter-based technologies.
- (d) In 2004, SV Health Investors and Incept invested in Sadra Medical, Inc. ("Sadra"), a medical device company that developed a technology used in structural heart therapies. Defendant Warden served as a director of Sadra from at least April 2004 to at least January 2006.
- 96. Due to the profitable nature of their relationship with defendant Sawhney, defendants Warden and Peacock will not agree to bring a lawsuit against him despite the fact that he faces a substantial likelihood of liability.
- 97. Defendants Warden, Peacock, and Garvey's allegiance to defendant Sawhney provide defendant Sawhney with a significant amount of influence over the Board. Together, defendants Sawhney, Warden, Peacock, and Garvey and the entities with which they are affiliated own almost 25% of Ocular's stock.⁸

⁶ Confluent Surgical was acquired by Covidien Ltd. in July 2006.

⁷ Incept is a venture capital firm that specializes in the incubation of healthcare and life-sciences companies. Defendant Sawhney is cofounder, a general partner, and a 50% owner of Incept.

⁸ Defendant Sawhney and the entities with which he is affiliated own 3,273,231 shares, or 11.1%, of Ocular stock. Defendant Garvey and the entities affiliated with Versant own 1,622,251 shares, or 5.6% of Ocular stock. Defendant Peacock owns 16,412 shares of Ocular stock. Defendant Warden owns 2,232,428, or 7.7%, of Ocular stock.

- 98. Defendant Sawhney's domination of the Board is also evidenced by the fact that he has caused Ocular to enter into multiple transactions with companies he is affiliated with, including:
- (a) Incept has listed Ocular as a portfolio company of Incept since 2006. Additionally, in 2006 the Company entered into a license agreement with Incept, pursuant to which Ocular has a right to use certain patents that are owned or controlled by Incept. The Company uses these patents to develop products designed to treat ophthalmic diseases and conditions. Ocular and Incept agreed to expand the scope of this license agreement in 2014.
- (b) Axtria, Inc. ("Axtria"), a data analytics company that provides consulting, outsourcing, and technology solutions to businesses. Defendant Sawhney is an Axtria director. Ocular has entered into multiple material agreements with Axtria, pursuant to which Axtria has provided various services to the Company including sales, marketing, analytics, and data warehouse implantation services.
- (c) Since 2012, Ocular has received approximately \$680,000 from Augmenix for consulting services the Company provided to Augmenix.
- 99. Additionally, defendants Sawhney and Chadha are cousins and attended the Indian Institute of Technology Delhi together from 1986 to 1987. Defendant Sawhney's placement of defendant Chadha on the Board demonstrates that he is willing to give his close allies lucrative director positions at a company he controls. The other members of the Board will not agree to bring an action against defendant Sawhney, as doing so would likely prevent defendant Sawhney from selecting them to serve as directors for one of his other companies or for a company he establishes in the future.

- 100. In sum, defendant Sawhney's domination of the Board is demonstrated by: (i) his role as Executive Chairman of the Board; (ii) his mutually beneficial business relationships with defendants Warden, Peacock, and Garvey, and their venture capital firms; (iii) his history of causing Ocular to transact business with entities he is affiliated with; and (iv) his placement of close allies on the Board. He faces a substantial likelihood of liability for the misconduct described herein. However, defendants Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea and nondefendant director Mattessich cannot objectively determine whether to bring an action against defendant Sawhney due to the influence he exerts over the Board. Accordingly, any demand made on defendants Warden, Lindstrom, Chadha, Peacock, Heier, and O'Shea and nondefendant director Mattessich is futile.
- 101. Defendants Peacock and Garvey have developed a close business relationship due to their concurrent affiliation with SV Health Investors. For this reason, defendant Peacock cannot objectively determine whether to bring a lawsuit against defendant Garvey, who faces a substantial likelihood of liability. Therefore, any demand made on defendant Peacock is futile.
- 102. Versant frequently coinvests with SV Health Investors. Due to the close business relationship between these firms, defendant Warden is unable to objectively determine whether to bring an action against defendants Peacock and Garvey, both of whom face a substantial likelihood of liability. For this same reason, defendant Peacock cannot objectively determine whether to bring an action against defendant Warden, who faces a substantial likelihood of liability. Accordingly, any demand made on these directors is futile.
- 103. In 2008, defendants Sawhney and Warden cofounded Frontier Management LLC ("Frontier"). Frontier is described as a "venture capital investment vehicle" in a filing with the California Secretary of State. Defendants Sawhney and Warden face a substantial likelihood of

liability for the misconduct described herein. However, due to the close, longstanding nature of their business relationship, these defendants cannot objectively determine whether to bring an action against one another. Therefore, any demand made on these defendants is futile.

104. Defendant Chadha cofounded Axtria. If defendants Warden and Peacock bring an action against defendant Chadha, defendant Chadha and other company founders may refuse to present SV Health Investors and Versant with investment opportunities. Moreover, bringing an action against defendant Chadha might cost defendants Warden and Peacock their Company director positions, as defendant Chadha is defendant Sawhney's cousin. Accordingly, defendants Warden and Peacock cannot objectively determine whether to bring an action against defendant Chadha, who faces a substantial likelihood of liability. Any demand made on defendants Warden and Peacock is futile.

attended the Indian Institute of Technology Delhi together. These defendants have also concurrently worked for multiple companies including Axtria from 2010 to the present and marketRx Inc. ("marketRx")⁹ in at least October 2003. Moreover, defendant Sawheny's Incept invested in Axtria in 2011, while defendant Chadha served as Axtria's CEO. Incept also invested in marketRx in 2002, while defendant Chadha served as marketRx's President and CEO. Due to the close nature of their familial relationship and their extensive business relationship, and the substantial likelihood of liability they face for the misconduct described herein, these defendants

⁹ marketRx was a corporation that provided sales and marketing solutions to pharmaceutical and biotechnology companies. marketRx was acquired by Cognizant Technology Solutions Corporation in November 2007. Defendant Chadha served as the Cofounder, President, and CEO of marketRx from 2000-2009. Defendants Chadha and Sawhney served as marketRx directors in at least October 2003.

cannot fairly determine whether to bring actions against one another. Therefore, any demand made on them would be futile.

These defendants have concurrently been employed at Incept since 2008. Since that year, defendant Sawhney has served as Incept's General Partner and defendant Ankerud has served as an Executive Vice President for the company. In addition, these defendants concurrently held executive positions at Augmenix from 2008 to April 2014. During that period, defendant Sawhney served as an Augmenix director and the company's CEO and defendant Ankerud served as an Augmenix Executive Vice President. As a result of his extensive business relationship with defendant Ankerud, and the substantial likelihood of liability defendant Ankerud faces for the misconduct described herein, defendant Sawhney cannot fairly determine whether to bring an action against him. Therefore, any demand made on defendant Sawhney is futile.

107. Additionally, defendants Sawhney, Warden, and Ankerud were concurrently affiliated with Confluent Surgical from 2002 to at least 2004. During that time, defendant Sawhney served as Confluent Surgical's President and CEO, defendant Ankerud served as Vice President of the company, and defendant Warden served as a company director. As a result of these business relationships, and the substantial likelihood of liability these defendants face for the misconduct described herein, defendant Sawhney cannot fairly determine whether to bring an action against defendants Warden and Ankerud. Likewise, defendant Warden cannot fairly determine whether to bring an action against defendants Sawhney and Ankerud. Accordingly, any demand made on defendants Sawhney and Warden is futile.

108. Defendants Sawhney and Smith were both affiliated with Focal, Inc. ("Focal") from 1993 to 1998.¹⁰ Focal developed, manufactured, and commercialized a family of biodegradable polymers based on proprietary technology. Defendant Smith faces a substantial likelihood of liability for the misconduct described herein. However, given their longstanding business relationship, defendant Sawhney cannot objectively determine whether to bring an action against defendant Smith. Accordingly, any demand made against defendant Sawhney is futile.

109. From 2003 to 2005, defendant Smith served as Chief Financial Officer of SYNARC, Inc. ("SYNARC"), a company that provides centralized medical imaging services and international subject-recruitment facilities dedicated exclusively to global clinical trials. SV Health Investors invested in SYNARC in March 2004, during defendant Smith's tenure as SYNARC's Chief Financial Officer. Defendant Smith faces a substantial likelihood of liability for the misconduct described herein. However, defendant Peacock cannot fairly determine whether to bring an action against defendant Smith, as doing so might prevent defendant Smith from presenting SV Health Investors with additional investment opportunities. Moreover, defendant Warden cannot objectively determine whether to bring an action against defendant Smith, as doing so might prevent defendant Smith from presenting Versant with future investment opportunities. Therefore, any demand made on defendants Warden and Peacock is futile.

110. Plaintiff has not made any demand on the other stockholders of Ocular to institute this action since such demand would be a futile and useless act for at least the following reasons:

¹⁰ Defendant Sawhney served as a Focal director from 1992 to 1998. Defendant Smith served as a Focal Vice President from 1994 to 2000 and as a Focal director from 1993 to 1994.

- (a) Ocular is a publicly held company with over 29.4 million shares outstanding and thousands of stockholders;
- (b) making demand on such a number of stockholders would be impossible for plaintiff who has no way of finding out the names, addresses, or phone numbers of stockholders; and
- (c) making demand on all stockholders would force plaintiff to incur excessive expenses, assuming all stockholders could be individually identified.

COUNT I

Against the Individual Defendants for Breach of Fiduciary Duty

- 111. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 112. The Individual Defendants owed and owe Ocular fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed and owe Ocular the highest obligation of good faith, fair dealing, loyalty, and due care.
- 113. The Individual Defendants and each of them, violated and breached their fiduciary duties of candor, good faith, and loyalty. More specifically, the Individual Defendants violated their duty of good faith by creating a culture of lawlessness within Ocular, and/or consciously failed to prevent the Company from engaging in the unlawful acts complained of herein.
- 114. The Individual Defendants also breached their fiduciary duties of loyalty by failing to correct the DEXTENZA manufacturing deficiencies identified in the 2016 Form 483. The Individual Defendants further breached their duties of loyalty by allowing worse manufacturing deficiencies, including product contamination issues and improperly trained

employees, to develop between the first and second FDA inspections of the DEXTENZA manufacturing facilities.

- 115. The Officer Defendants either knew, were reckless, or were grossly negligent in disregarding the illegal activity of such substantial magnitude and duration. The Officer Defendants either knew, were reckless, or were grossly negligent in not knowing: (i) that serious deficiencies in the DEXTENZA manufacturing process jeopardized the drug's FDA approval prospects; and (ii) that Ocular's statements regarding DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies were improper. Accordingly, the Officer Defendants breached their duty of care and loyalty to the Company.
- 116. The Director Defendants, as directors of the Company, owed Ocular the highest duty of loyalty. These defendants breached their duty of loyalty by recklessly permitting the improper activity concerning DEXTENZA's manufacturing and NDA approval processes. The Director Defendants either knew or were reckless in not knowing: (i) that serious deficiencies in the DEXTENZA manufacturing process jeopardized the drug's FDA approval prospects; and (ii) that Ocular's statements regarding DEXTENZA's FDA approval prospects, deficiencies in the drug's manufacturing process, and the Company's progress in resolving these deficiencies were improper. Accordingly, the Director Defendants breached their duty of loyalty to the Company.
- 117. The Audit Committee Defendants breached their fiduciary duty of loyalty by knowingly or recklessly allowing Ocular to file the misleading 2015 Form 10-K, issue the misleading May 5, 2017 earnings press release, and file the misleading May 5, 2017 Form 10-Q, in violation of the duties provided in the Audit Committee Charter in effect at the time. The Audit Committee Defendants also breached their duty of loyalty by knowingly or recklessly

failing to discuss the Company's policies regarding risk assessment, management, and exposure, as required by the Audit Committee Charter in effect at the time.

- 118. Defendant Garvey breached his duty of loyalty by knowingly or recklessly causing the SV Entities to sell their shares of Ocular stock on the basis of the knowledge of the improper information described above before that information was revealed to the Company's stockholders. The information described above was proprietary, nonpublic information concerning the Company's future business prospects. It was a proprietary asset belonging to the Company, which defendant Garvey used for his own benefit when he caused the SV Entities to sell Ocular common stock.
- 119. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, Ocular has sustained significant damages, as alleged herein. As a result of the misconduct alleged herein, these defendants are liable to the Company.
 - 120. Plaintiff, on behalf of Ocular, has no adequate remedy at law.

COUNT II

Against the Individual Defendants for Waste of Corporate Assets

- 121. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 122. The Individual Defendants breached their fiduciary duties to the Company by certifying the transfer of substantial corporate assets towards the manufacturing of significant quantities of contaminated DEXTENZA as a result of serious deficiencies in the drug's manufacturing process, for which no consideration at all will be received. As a result of these severe manufacturing deficiencies, the FDA has rejected Ocular's NDA for DEXTENZA twice, delaying and potentially preventing the commercial release of the critical product candidate. By

allowing the Company to continue manufacturing DEXTENZA, despite the deficiencies in its manufacturing process, the Individual Defendants have committed corporate waste in an exchange that no business person of ordinary and sound judgment could conclude resulted in adequate consideration.

- 123. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.
 - 124. Plaintiff, on behalf of Ocular, has no adequate remedy at law.

COUNT III

Against the Individual Defendants for Unjust Enrichment

- 125. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.
- 126. By their wrongful acts and omissions, the Individual Defendants were unjustly enriched at the expense of and to the detriment of Ocular. The Individual Defendants were unjustly enriched as a result of the compensation and director remuneration they received while breaching fiduciary duties owed to Ocular.
- 127. Defendant Garvey caused the SV Entities to sell Ocular stock while in possession of material, nonpublic information that artificially inflated the price of Ocular stock. As a result, defendant Garvey profited from his misconduct and was unjustly enriched through his exploitation of material and adverse inside information.
- 128. Plaintiff, as a stockholder and representative of Ocular, seeks restitution from these defendants, and each of them, and seeks an order of this Court disgorging all profits, benefits, and other compensation obtained by these defendants, and each of them, from their wrongful conduct and fiduciary breaches.

129. Plaintiff, on behalf of Ocular, has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of Ocular, demands judgment as follows:

- A. Against all of the defendants and in favor of the Company for the amount of damages sustained by the Company as a result of the defendants' breaches of fiduciary duties, waste of corporate assets, and unjust enrichment;
- B. Directing Ocular to take all necessary actions to reform and improve its corporate governance and internal procedures to comply with applicable laws and to protect Ocular and its stockholders from a repeat of the damaging events described herein, including, but not limited to, putting forward for stockholder vote, resolutions for amendments to the Company's By-Laws or Articles of Incorporation and taking such other action as may be necessary to place before stockholders for a vote of the following Corporate Governance Policies:
- 1. a proposal to strengthen the Company's controls over its product manufacturing processes;
 - 2. a proposal to strengthen Ocular's oversight of its disclosure procedures;
- 3. a proposal to strengthen the Board's supervision of operations and develop and implement procedures for greater stockholder input into the policies and guidelines of the Board; and
- 4. a provision to permit the stockholders of Ocular to nominate at least three candidates for election to the Board;
- C. Extraordinary equitable and/or injunctive relief as permitted by law, equity, and state statutory provisions sued hereunder, including attaching, impounding, imposing a

constructive trust on, or otherwise restricting the proceeds of defendants' trading activities or

their other assets so as to assure that plaintiff on behalf of Ocular has an effective remedy;

D. Awarding to Ocular restitution from defendants, and each of them, and ordering

disgorgement of all profits, benefits, and other compensation obtained by the defendants,

including all ill-gotten gains from insider selling by defendant Garvey;

E. Awarding to plaintiff the costs and disbursements of the action, including

reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

F. Granting such other and further relief as the Court deems just and proper.

JURY DEMAND

Plaintiff demands a trial by jury.

Dated: January 31, 2018

/s/Peter Charles Horstmann

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